

WE CLAIM:

1. A sensor comprising:

5 a first substrate having a first major surface and a second major surface opposing the first major surface;

a second substrate having a first major surface and a second major surface opposing the first major surface, the first and second substrates being disposed so that the first major surface of the first substrate is in facing relationship with the first major surface of the second substrate;

10 a working electrode disposed on the first major surface of the first substrate;

a counter electrode disposed on the first major surface of one of the first substrate and the second substrate; and

an insertion monitor disposed on the second major surface of one of the first substrate and the second substrate, the insertion monitor being configured and arranged to provide a path for electrical current between at least two contact leads of a meter for indication that the sensor has been properly inserted into the meter.

2. The sensor according to claim 1, wherein the insertion monitor is disposed on the second major surface of the first substrate.

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3. The sensor according to claim 1, wherein the counter electrode is disposed on the first major surface of the second substrate.

4. The sensor according to claim 1, wherein the sensor has a width, and the insertion monitor is a conductive stripe extending across the width of the sensor.

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5. The sensor according to claim 1, wherein the insertion monitor has two or more contact regions for electrical contact with the meter.

6. The sensor of claim 1, wherein the insertion monitor is configured and arranged to provide encoded information about the strip.

7. A sensor strip comprising:

5 a first substrate having a first major surface and a second major surface opposing the first major surface;

a second substrate having a first major surface and a second major surface opposing the first major surface, the first and second substrates being disposed so that the first major surface of the first substrate is in facing relationship with the first major surface of the second substrate;

10 a working electrode disposed on the first major surface of the first substrate;

a counter electrode disposed on the first major surface of one of the first substrate and the second substrate; and

a plurality of contact pads disposed on the first and second substrates, at least one of the contact pads being in electrical communication with the working electrode and at least one other contact pad being in electrical communication with the counter electrode, wherein each contact pad has a contact pad width measured parallel to a width of the first and second substrates, and wherein the sum of the contact pad widths is greater than the width of the first substrate and greater than the width of the second substrate.

8. The sensor strip of claim 7 wherein the plurality of contact pads are disposed on at least three of the following surfaces: the first major surface of the first substrate, the second major surface of the first substrate, the first major surface of the second substrate, and the second major surface of the second substrate.

9. A connector comprising:

a plurality of contact structures for releasable connection to an electrochemical analyte sensor, wherein each contact lead comprises

a proximal end for electrical connection to a sensor contact, and
a distal end for electrical connection to an electrical device; and
wherein the plurality of contact leads comprises
one or more first contact leads extending longitudinally from the distal
5 end to the proximal end, and
one or more second contact leads extending longitudinally from the
distal end past the proximal end of the one or more first contact
leads and angling toward a longitudinal center line of the sensor.

10 10. The connector of claim 9, wherein the connector comprises at least two second
contact leads to make electrical contact with a single conductive surface of the sensor.

11. The connector of claim 10, wherein the first contact leads are configured and
arranged to contact at least one of a working electrode and a counter electrode of a
15 sensor, and wherein the second contact leads are configured and arranged to contact an
insertion monitor of a sensor.

12. A method for the manufacture of a sensor comprising the steps of:
providing an adhesive having first and second surfaces covered with first and
20 second release liners;
cutting through the first release liner but not through the second release liner to
define a plurality of sample chamber regions;
removing a portion of the first release liner to expose a portion of the first
adhesive surface leaving a remaining portion of the first release liner
25 over the sample chamber regions;
applying the exposed first adhesive surface to a first substrate;
removing the second release liner together with the adhesive and first release
liner of the sample chamber regions to expose the second adhesive
surface and to expose the first substrate in the sample chamber region;

and

applying a second substrate over the second adhesive surface forming a sample chamber in the sample chamber region, wherein a plurality of conductive traces are disposed on the first substrate, the second substrate, or a combination thereof, the conductive traces defining at least one working electrode and at least one counter electrode, and the sample chambers are disposed to allow an analyte sample disposed in the sample chambers to be electrolyzed by a current flowing between the working electrode and the counter electrode; and

separating a plurality of electrochemical sensors, each electrochemical sensor comprising at least one of the working electrodes, at least one of the counter electrodes, and at least one of the sample chambers.

13. The method of claim 12 wherein the working electrodes are disposed on one of the substrates and the counter electrodes are disposed on the other substrate.

14. A method for determining a concentration of an analyte in a body fluid sample, the method comprising steps of:

disposing a body fluid sample in a sample chamber of an electrochemical sensor, the electrochemical sensor further comprising at least one working electrode and at least one counter electrode for electrolyzing an analyte in the body fluid sample in the sample chamber of the electrochemical sensor;

electrolyzing at least a portion of an analyte in the body fluid sample by causing a current to flow between the at least one working electrode and the at least one counter electrode;

determining, during the electrolyzing of the analyte, a plurality of current values, at least some of the current values being obtained while the electrolysis of the analyte in the sensor is substantially diffusion limited;

determining, from the current values obtained while the electrolysis of the
analyte in the sensor is substantially diffusion limited, parameters for
extrapolation of a relationship between the current values and time;
determining from the plurality of current values the amount of an actual charge
5 consumed in the partial electrolysis of the analyte in the sample;
determining, from the parameters for extrapolation of the relationship between
the current values and time, an extrapolated charge required to
electrolyze the analyte remaining in the sample;
determining the concentration of the analyte in the body fluid sample from the
10 actual charge and the extrapolated charge.

15. The method of claim 14, wherein the step of determining parameters for
extrapolation of the relationship between current values and time comprises determining
a value related to a diffusion coefficient of the analyte in the sensor.

16. The method of claim 14, wherein the step of determining parameters for
extrapolation of the relationship between current values and time comprises determining
a slope of a natural logarithm of current values versus time obtained while the
electrolysis of the analyte in the sensor is substantially diffusion limited.

17. An electrochemical sensor device comprising:

- (a) an electrochemical sensor comprising
 - (i) at least one working electrode,
 - (ii) at least one counter electrode, and
 - 25 (iii) a sample chamber for holding a body fluid sample in electrolytic
contact with the at least one working electrode and at least one
counter electrode; and
- (b) a processor coupled to the electrochemical sensor, the processor being
configured and arranged to

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- (i) electrolyze at least a portion of an analyte in the body fluid sample by causing a current to flow between the at least one working electrode and at least one counter electrode;
- (ii) determine, during the electrolyzing of the analyte, a plurality of current values, at least some of the current values being obtained while the electrolysis of the analyte in the sensor is substantially diffusion limited;
- 10 (iii) determine, from the current values obtained while the electrolysis of the analyte in the sensor is substantially diffusion limited, parameters for extrapolation of a relationship between the current values and time;
- (iv) determine the amount of an actual charge consumed in the partial electrolysis of the analyte in the sample;
- 15 (v) determine an extrapolated charge required to electrolyze the analyte remaining in the sample; and
- (vi) determine, from the actual charge and the extrapolated charge, the concentration of the analyte in the body fluid sample.

18. A method of determining an amount of current used to electrolyze a portion of an analyte in a body fluid sample disposed in an electrochemical sensor, the method comprising:

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discharging an amount of charge into the body fluid sample disposed in the electrochemical sensor and electrolyzing the analyte;

determining an amount of time needed to discharge the amount of charge; and

25 determining the current used to electrolyze the portion of the analyte using the amount of charge and the amount of time.

19. The method of claim 18 wherein the charge is provided by the discharge of a capacitor.

20. The method of claim 19, further comprising calibrating the capacitor by discharging the capacitor through a resistor of known resistance and measuring either a current or a time constant associated with the discharge.

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21. An electrochemical sensor device, comprising:

(a) an electrochemical sensor comprising

(i) at least one working electrode,

(ii) at least one counter electrode, and

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(iii) a sample chamber for holding a body fluid sample in electrolytic contact with the at least one working electrode and at least one counter electrode; and

(b) a measuring device comprising

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(i) a capacitor configured and arranged for coupling to the at least one working electrode to repeatedly deliver an amount of charge by repeatedly discharging, for electrolyzing at least a portion of an analyte in a body fluid disposed in the sample chamber,

(ii) a clock to measure discharge times of the capacitor, and

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(iii) a processor to determine a concentration of the analyte in the body fluid based on the discharge times.

22. A sensor comprising:

a first substrate having a first major surface and a second major surface opposing the first major surface;

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a second substrate having a first major surface and a second major surface opposing the first major surface, the first and second substrates being disposed so that the first major surface of the first substrate is in facing relationship with the first major surface of the second substrate;

a working electrode disposed on the first major surface of the first substrate;

a counter electrode disposed on the first major surface of one of the first substrate and the second substrate; and

a conductive trace positioned on the second major surface of one of the first substrate and the second substrate, the conductive trace electrically connected to two or
5 more contact pads for electrical contact with a connector, the conductive trace configured and arranged to close an electrical circuit, and wherein conductive trace has a resistance that carries information related to the sensor.